

6081386

510(k) Summary  
MyLab70, 90 Systems  
Esaote, S.p.A.

SEP 25 2008

## 510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR§807.92(a).

### 807.92(a)(1)

#### Submitter Information

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Contact Person: Allison Scott

Date: August 12, 2008

### 807.92(a)(2)

Trade Name: MyLab70 & MyLab90 Systems

Common Name: Ultrasound Imaging System

Classification Name(s): Ultrasonic pulse doppler imaging system 892.1550  
Ultrasonic pulsed echo imaging system 892.1560

Classification Number: 90IYN; 90IYO

### 807.92(a)(3)

#### Predicate Device(s)

K070106, K062086,  
K042391, K012564, and  
K042512

BrainLab

IGSonic

K051308

MyLab70

Esaote, S.p.A.

K051837

MyLab90

Esaote, S.p.A.

K060827

MyLab 70, 90

Esaote, S.p.A.

K013722

RVS

Hitachi

807.92 (a)(4)

### **Device Description**

The MyLab70 and MyLab90 system designs remain the same as those previously cleared by FDA via K051837, K051308, and K060827, respectively, except for those features being added via this submission.

They are compact ultrasound systems used to perform diagnostic general ultrasound studies. Their primary modes of operation are: B-Mode, M-Mode, Doppler and Color Flow Mapping and, on lower frequency probes and, Tissue Enhancement Imaging (TEI). The systems are equipped with an optional LCD Color Display and can drive phased (PA), convex (CA) and linear array (LA) and Doppler probes.

The MyLab70 and MyLab90 systems are able to produce Real Time 2D images and 3D images (in manual mode) with all probes. The MyLab70 and MyLab90 systems are manufactured under an ISO 9001:2000 and ISO 13485 certified quality system.

807.92(a)(5)

### **Intended Use(s)**

Esaote's Model 6150 (MyLab70) and Model 6100 (MyLab90) are mainframe ultrasound systems used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative: Abdominal, and Other: Urologic. Additionally, the MyLab90 is indicated for Laparoscopic use.

The Virtual Navigator is a MyLab optional license that provides additional image information from a second modality like CT or MR, during a clinical ultrasound session. The second modality provides additional security in assessing the morphology of the ultrasound image.

Virtual Navigator can be used in the following application: Abdominal, Musculo-skeletal, Urologic, and Vascular.

The second modality image is not intended to be used as a standalone diagnostic image since it represents information of a patient that could not be congruent with the current (actual) patient position and shall therefore always be seen as an **additional** source of information.

The Virtual Navigator tracking system should not be used on or around persons with a cardiac pacemaker, and should not be used around life supporting equipment.

807.92(a)(6)

**Technological Characteristics**

|                            | <b>Hitachi RVS<br/>K013722<br/>Predicate</b> | <b>IGSonic<br/>BrainLab<br/>K012564<br/>Predicate</b> | <b>Esaote<br/>MyLab 90<br/>(6100)<br/>K051837</b>  | <b>Esaote<br/>MyLab 70<br/>(6150)<br/>K051308</b>  |
|----------------------------|--|---|--|--|
| Virtual Navigator software | YES  | YES   | To be cleared with this submission   | To be cleared with this submission   |
| Primary application        | Abdominal                                    | NeuroSurgery  | Abdominal, Musculoskeletal Conventional and Superficial, Peripheral Vascular and, Urologic | Abdominal, Musculoskeletal Conventional & Superficial, Peripheral Vascular and, Urologic |
| Tracking System            | Electromagnetic (Ascension)                  | Optical (NDI)   | Electromagnetic (Ascension)  | Electromagnetic (Ascension)  |
| Registration Procedure     | External Marker – one scan plane             | External Marker                                       | External and Internal Marker, one scan plane   | External and Internal Marker, one scan plane   |



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 25 2008

Esaote, S.p.A.  
% Mr. Mark Job  
Responsible Third Party Official  
Regulatory Technology Services LLC  
1394 25<sup>th</sup> Street NW  
BUFFALO MN 55313

Re: K081386

Trade/Device Name: MyLab70 and MyLab90 Systems  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulatory Class: II  
Product Code: IYN, IYO, and ITX  
Dated: September 9, 2008  
Received: September 10, 2008

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the MyLab70 and MyLab90 Systems, as described in your premarket notification:

Transducer Model Number

|        |        |        |
|--------|--------|--------|
| CA 421 | CA 631 | LA 523 |
| CA 430 | EC 123 | LA 532 |
| CA 431 | LA 435 | PA 122 |
| CA 621 | LA 522 | PA 230 |

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all

the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

If you have any questions regarding the content of this letter, please contact Ms. Lauren Hefner at (240) 276-3666.

Sincerely yours,



Joyce M. Whang, Ph.D.  
Acting Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known):

K081386

Device Name: MyLab70 and MyLab90 Systems

Indications For Use:

Esaote's Model 6150 (MyLab70) and Model 6100 (MyLab90) are mainframe ultrasound systems used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative: Abdominal, and Other: Urologic. Additionally, the MyLab90 is indicated for Laparoscopic use.

The Virtual Navigator is a MyLab optional license that provides additional image information from a second modality like CT or MR, during a clinical ultrasound session. The second modality provides additional security in assessing the morphology of the ultrasound image.

Virtual Navigator can be used in the following application: Abdominal, Musculo-skeletal, Urologic, and Vascular.

The second modality image is not intended to be used as a standalone diagnostic image since it represents information of a patient that could not be congruent with the current (actual) patient position and shall therefore always be seen as an **additional** source of information.

The Virtual Navigator tracking system should not be used on or around persons with a cardiac pacemaker, and should not be used around life supporting equipment.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

  
(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number \_\_\_\_\_

K081386

# MyLab90 & 70XVG

| Mode of Operations                |              |              |              |              |               |                   |              |                                      |                                  |              |                        |
|-----------------------------------|--------------|--------------|--------------|--------------|---------------|-------------------|--------------|--------------------------------------|----------------------------------|--------------|------------------------|
| Clinical Application              | B            | M            | PWD          | CWD          | Color Doppler | Amplitude Doppler | Combined [4] | Color Velocity Mapping (TVM) K051837 | Tissue Enhancement Imaging (TEI) | CNTI K051837 | Other (specify)        |
| Ophthalmic                        |              |              |              |              |               |                   |              |                                      |                                  |              |                        |
| Fetal                             | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837  | P<br>K051837      | P<br>K051837 | P<br>K051837                         | P<br>K051837                     | P<br>K051837 | 6, 7, 8, 9, 12         |
| Abdominal                         | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837  | P<br>K051837      | P<br>K051837 | P<br>K051837                         | P<br>K051837                     | P<br>K051837 | 6, 7, 8, 9, 12, 13     |
| Intraoperative (Abdominal)        | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837  | P<br>K051837      | P<br>K051837 | P<br>K051837                         | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12, 13        |
| Intraoperative Neurological       |              |              |              |              |               |                   |              |                                      |                                  |              |                        |
| Pediatric                         | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837  | P<br>K051837      | P<br>K051837 | P<br>K051837                         | P<br>K051837                     | P<br>K051837 | 6, 7, 8, 9, 12, 13     |
| Small Organ [1]                   | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837  | P<br>K051837      | P<br>K051837 | P<br>K051837                         | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12, 13        |
| Neonatal Cephalic                 | K051837      | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837  | P<br>K051837      | P<br>K051837 | P<br>K051837                         | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12            |
| Adult Cephalic                    | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837  | P<br>K051837      | P<br>K051837 | P<br>K051837                         | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12            |
| Cardiac [2] (M3369)               | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837  | P<br>K051837      | P<br>K051837 | P<br>K051837                         | P<br>K051837                     | P<br>K051837 | 6, 7, 8, 9, 12         |
| Transesophageal (Cardiac)         | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837  | P<br>K051837      | P<br>K051837 | P<br>K051837                         | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12            |
| Transesophageal (Non Cardiac)     | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837  | P<br>K051837      | P<br>K051837 | P<br>K051837                         | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12, 13        |
| Transrectal                       | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837  | P<br>K051837      | P<br>K051837 | P<br>K051837                         | P<br>K051837                     | P<br>K051837 | 6, 7, 8, 9, 12, 13, 14 |
| Transvag/nal                      | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837  | P<br>K051837      | P<br>K051837 | P<br>K051837                         | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12            |
| Transurethral                     |              |              |              |              |               |                   |              |                                      |                                  |              |                        |
| Intravascular                     |              |              |              |              |               |                   |              |                                      |                                  |              |                        |
| Peripheral Vascular               | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837  | P<br>K051837      | P<br>K051837 | P<br>K051837                         | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12            |
| Laparoscopic                      | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837  | P<br>K051837      | P<br>K051837 | P<br>K051837                         | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12, 13        |
| Musculo-skeletal Conventional [3] | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837  | P<br>K051837      | P<br>K051837 | P<br>K051837                         | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12, 13        |
| Musculo-skeletal Superficial [3]  | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837  | P<br>K051837      | P<br>K051837 | P<br>K051837                         | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12, 13        |
| Other [Urological]                | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837  | P<br>K051837      | P<br>K051837 | P<br>K051837                         | P<br>K051837                     | P<br>K051837 | 6, 7, 8, 9, 12, 13     |

N = New; P = Previously Cleared by FDA

[1] Small Organs Includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal Includes Nerve Block MF377

[4] Combined

[6] 3D K060827 & MF369

[7] 4D K060827 & MF369

[8] VPan K051837 & MF374

[9] XView K051837

[12] Compound K051837

[13] TP-View MF374

[14] IMT MF374

Concurrence of CDRH, Office of Device Evaluation (ODE)

*[Signature]*

(Division Sign-Off)  
Division of Reproductive, Abdominal and Radiological Devices  
510(k) Number K081386

Prescription Use (Per 21 CFR 801.109)

# MyLab90 & 70XVG - CA421

| Mode of Operations                |              |              |              |     |               |                   |              |                              |                                  |              |                 |
|-----------------------------------|--------------|--------------|--------------|-----|---------------|-------------------|--------------|------------------------------|----------------------------------|--------------|-----------------|
| Clinical Application              | B            | M            | PWD          | CWD | Color Doppler | Amplitude Doppler | Combined [4] | Color Velocity Mapping (TVM) | Tissue Enhancement Imaging (TEI) | CnTI         | Other (specify) |
| Ophthalmic                        |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Fetal                             | P<br>K051837 | P<br>K051837 | P<br>K051837 |     | P<br>K051837  | P<br>K051837      | P<br>K051837 |                              | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12     |
| Abdominal                         | P<br>K051837 | P<br>K051837 | P<br>K051837 |     | P<br>K051837  | P<br>K051837      | P<br>K051837 |                              | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12     |
| Intraoperative (Abdominal)        |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Intraoperative Neurological       |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Pediatric                         | P<br>K051837 | P<br>K051837 | P<br>K051837 |     | P<br>K051837  | P<br>K051837      | P<br>K051837 |                              | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12     |
| Small Organ [1]                   |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Neonatal Cephalic                 |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Adult Cephalic                    |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Cardiac [2]                       |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Adult Cephalic                    |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Transesophageal (Non Cardiac)     |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Transrectal                       |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Transvaginal                      |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Transurethral                     |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Intravascular                     |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Peripheral Vascular               | P<br>K051837 | P<br>K051837 | P<br>K051837 |     | P<br>K051837  | P<br>K051837      | P<br>K051837 |                              | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12     |
| Laparoscopic                      |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Musculo-skeletal Conventional [3] | P<br>MF374   | P<br>MF374   | P<br>MF374   |     | P<br>MF374    | P<br>MF374        | P<br>MF374   |                              | P<br>MF374                       | P<br>MF374   | 6, 8, 9, 12     |
| Musculo-skeletal Superficial [3]  | P<br>MF374   | P<br>MF374   | P<br>MF374   |     | P<br>MF374    | P<br>MF374        | P<br>MF374   |                              | P<br>MF374                       | P<br>MF374   | 6, 8, 9, 12     |
| Other (Urological)                | P<br>K051837 | P<br>K051837 | P<br>K051837 |     | P<br>K051837  | P<br>K051837      | P<br>K051837 |                              | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12     |

N = New; P = Previously Cleared by FDA

[8] VPan - MTF 374

[3] Musculoskeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[6] 3D K051837

[12] Compound K051837

Concurrence of CDRH, Office of Device Evaluation (ODE)

*[Signature]*  
(Division Sign-Off)

Division of Reproductive, Abdominal and  
Radiological Devices  
510(k) Number K081386



# MyLab90 & 70XVG - CA430

| Mode of Operations                |              |              |              |     |               |                   |              |                              |                                  |              |                 |
|-----------------------------------|--------------|--------------|--------------|-----|---------------|-------------------|--------------|------------------------------|----------------------------------|--------------|-----------------|
| Clinical Application              | B            | M            | PWD          | CWD | Color Doppler | Amplitude Doppler | Combined [4] | Color Velocity Mapping (TVM) | Tissue Enhancement Imaging (TEI) | CnTI         | Other (specify) |
| Ophthalmic                        |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Fetal                             | P<br>K051837 | P<br>K051837 | P<br>K051837 |     | P<br>K051837  | P<br>K051837      | P<br>K051837 |                              | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12     |
| Abdominal                         | P<br>K051837 | P<br>K051837 | P<br>K051837 |     | P<br>K051837  | P<br>K051837      | P<br>K051837 |                              | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12     |
| Intraoperative (Abdominal)        |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Intraoperative Neurological       |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Pediatric                         | P<br>MIF374  | P<br>MIF374  | P<br>MIF374  |     | P<br>MIF374   | P<br>MIF374       | P<br>MIF374  |                              | P<br>MIF374                      | P<br>MIF374  | 6, 8, 9, 12     |
| Small Organ [1]                   |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Neonatal Cephalic                 |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Adult Cephalic                    |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Cardiac [2]                       |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Adult Cephalic                    |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Transesophageal (Non Cardiac)     |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Transrectal                       |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Transvaginal                      |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Transurethral                     |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Intravascular                     |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Peripheral Vascular               | P<br>K051837 | P<br>K051837 | P<br>K051837 |     | P<br>K051837  | P<br>K051837      | P<br>K051837 |                              | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12     |
| Laparoscopic                      |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Musculo-skeletal Conventional [3] | P<br>MIF374  | P<br>MIF374  | P<br>MIF374  |     | P<br>MIF374   | P<br>MIF374       | P<br>MIF374  |                              | P<br>MIF374                      | P<br>MIF374  | 6, 8, 9, 12     |
| Musculo-skeletal Superficial [3]  | P<br>MIF374  | P<br>MIF374  | P<br>MIF374  |     | P<br>MIF374   | P<br>MIF374       | P<br>MIF374  |                              | P<br>MIF374                      | P<br>MIF374  | 6, 8, 9, 12     |
| Other (Urological)                | P<br>MIF374  | P<br>MIF374  | P<br>MIF374  |     | P<br>MIF374   | P<br>MIF374       | P<br>MIF374  |                              | P<br>MIF374                      | P<br>MIF374  | 6, 8, 9, 12     |

N = New; P = Previously Cleared by FDA

[3] Musculoskeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[6] 3D K051837

[8] VPan - MTF 374

[9] XView - K051837

[12] Compound K051837

Concurrence of CDRH, Office of Device Evaluation (ODE)

*[Signature]*

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number K081 386

Prescription Use (Per 21 CFR 801.109)

# MyLab90 & 70XVG - CA431

| Mode of Operations                |            |            |            |     |               |                   |              |                              |                                  |            |                 |
|-----------------------------------|------------|------------|------------|-----|---------------|-------------------|--------------|------------------------------|----------------------------------|------------|-----------------|
| Clinical Application              | B          | M          | PWD        | CWD | Color Doppler | Amplitude Doppler | Combined [4] | Color Velocity Mapping (TVM) | Tissue Enhancement Imaging (TEI) | ChTI       | Other (specify) |
| Ophthalmic                        |            |            |            |     |               |                   |              |                              |                                  |            |                 |
| Fetal                             | P<br>MF329 | P<br>MF329 | P<br>MF329 |     | P<br>MF329    | P<br>MF329        | P<br>MF329   |                              | P<br>MF329                       | P<br>MF329 | 6, 8, 9         |
| Abdominal                         | P<br>MF329 | P<br>MF329 | P<br>MF329 |     | P<br>MF329    | P<br>MF329        | P<br>MF329   |                              | P<br>MF329                       | P<br>MF329 | 6, 8, 9         |
| Intraoperative (Abdominal)        |            |            |            |     |               |                   |              |                              |                                  |            |                 |
| Intraoperative Neurological       |            |            |            |     |               |                   |              |                              |                                  |            |                 |
| Pediatric                         | P<br>MF329 | P<br>MF329 | P<br>MF329 |     | P<br>MF329    | P<br>MF329        | P<br>MF329   |                              | P<br>MF329                       |            | 6, 8, 9         |
| Small Organ [1]                   |            |            |            |     |               |                   |              |                              |                                  |            |                 |
| Neonatal Cephalic                 |            |            |            |     |               |                   |              |                              |                                  |            |                 |
| Adult Cephalic                    |            |            |            |     |               |                   |              |                              |                                  |            |                 |
| Cardiac [2]                       |            |            |            |     |               |                   |              |                              |                                  |            |                 |
| Adult Cephalic                    |            |            |            |     |               |                   |              |                              |                                  |            |                 |
| Transesophageal (Non Cardiac)     |            |            |            |     |               |                   |              |                              |                                  |            |                 |
| Transrectal                       |            |            |            |     |               |                   |              |                              |                                  |            |                 |
| Transvaginal                      |            |            |            |     |               |                   |              |                              |                                  |            |                 |
| Transurethral                     |            |            |            |     |               |                   |              |                              |                                  |            |                 |
| Intravascular                     |            |            |            |     |               |                   |              |                              |                                  |            |                 |
| Peripheral Vascular               | P<br>MF329 | P<br>MF329 | P<br>MF329 |     | P<br>MF329    | P<br>MF329        | P<br>MF329   |                              | P<br>MF329                       | P<br>MF329 | 6, 8, 9         |
| Laparoscopic                      |            |            |            |     |               |                   |              |                              |                                  |            |                 |
| Musculo-skeletal Conventional [3] | P<br>MF329 | P<br>MF329 | P<br>MF329 |     | P<br>MF329    | P<br>MF329        | P<br>MF329   |                              | P<br>MF329                       | P<br>MF329 | 6, 8, 9         |
| Musculo-skeletal Superficial [3]  | P<br>MF329 | P<br>MF329 | P<br>MF329 |     | P<br>MF329    | P<br>MF329        | P<br>MF329   |                              | P<br>MF329                       | P<br>MF329 | 6, 8, 9         |
| Other (Urological)                | P<br>MF329 | P<br>MF329 | P<br>MF329 |     | P<br>MF329    | P<br>MF329        | P<br>MF329   |                              | P<br>MF329                       | P<br>MF329 | 6, 8, 9         |

N = New; P = Previously Cleared by FDA

[3] Musculoskeletal - Nerve Block

[4] Combined modes

are: B+M+PW+CFM+PD

[6] 3D KOS1837

[8] VPan - MTF 374

[9] XView - KOS1837

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal and  
Radiological Devices  
510(k) Number K081386

Prescription Use (Per 21 CFR 801.109)

# MyLab90 & 70 XVG - CA621

|                                   | Mode of Operations |              |              |     |               |                   |              |                              |                                  |              |                 |
|-----------------------------------|--------------------|--------------|--------------|-----|---------------|-------------------|--------------|------------------------------|----------------------------------|--------------|-----------------|
| Clinical Application              | B                  | M            | PWD          | CWD | Color Doppler | Amplitude Doppler | Combined [4] | Color Velocity Mapping (TVM) | Tissue Enhancement Imaging (TEI) | CnTI         | Other (specify) |
| Ophthalmic                        |                    |              |              |     |               |                   |              |                              |                                  |              |                 |
| Fetal                             | P<br>K051837       | P<br>K051837 | P<br>K051837 |     | P<br>K051837  | P<br>K051837      | P<br>K051837 |                              | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12     |
| Abdominal                         | P<br>K051837       | P<br>K051837 | P<br>K051837 |     | P<br>K051837  | P<br>K051837      | P<br>K051837 |                              | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12     |
| Intraoperative (Abdominal)        |                    |              |              |     |               |                   |              |                              |                                  |              |                 |
| Intraoperative Neurological       |                    |              |              |     |               |                   |              |                              |                                  |              |                 |
| Pediatric                         | P<br>MIF374        | P<br>MIF374  | P<br>MIF374  |     | P<br>MIF374   | P<br>MIF374       | P<br>MIF374  |                              | P<br>MIF374                      | P<br>MIF374  | 6, 8, 9, 12     |
| Small Organ [1]                   |                    |              |              |     |               |                   |              |                              |                                  |              |                 |
| Neonatal Cephalic                 |                    |              |              |     |               |                   |              |                              |                                  |              |                 |
| Adult Cephalic                    |                    |              |              |     |               |                   |              |                              |                                  |              |                 |
| Cardiac [2]                       |                    |              |              |     |               |                   |              |                              |                                  |              |                 |
| Adult Cephalic                    |                    |              |              |     |               |                   |              |                              |                                  |              |                 |
| Transesophageal (Non Cardiac)     |                    |              |              |     |               |                   |              |                              |                                  |              |                 |
| Transrectal                       |                    |              |              |     |               |                   |              |                              |                                  |              |                 |
| Transvaginal                      |                    |              |              |     |               |                   |              |                              |                                  |              |                 |
| Transurethral                     |                    |              |              |     |               |                   |              |                              |                                  |              |                 |
| Intravascular                     |                    |              |              |     |               |                   |              |                              |                                  |              |                 |
| Peripheral Vascular               | P<br>K051837       | P<br>K051837 | P<br>K051837 |     | P<br>K051837  | P<br>K051837      | P<br>K051837 |                              | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12     |
| Laparoscopic                      |                    |              |              |     |               |                   |              |                              |                                  |              |                 |
| Musculo-skeletal Conventional [3] | P<br>MIF374        | P<br>MIF374  | P<br>MIF374  |     | P<br>MIF374   | P<br>MIF374       | P<br>MIF374  |                              | P<br>MIF374                      | P<br>MIF374  | 6, 8, 9, 12     |
| Musculo-skeletal Superficial [3]  | P<br>MIF374        | P<br>MIF374  | P<br>MIF374  |     | P<br>MIF374   | P<br>MIF374       | P<br>MIF374  |                              | P<br>MIF374                      | P<br>MIF374  | 6, 8, 9, 12     |
| Other (Urological)                | P<br>K051837       | P<br>K051837 | P<br>K051837 |     | P<br>K051837  | P<br>K051837      | P<br>K051837 |                              | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12     |

N = New; P = Previously Cleared by FDA

[3] Musculoskeletal - Nerve Block

[4] Combined modes

are: B+M+PW+CFM+PD

[6] 3D K051837

[8] VPan - MTF 374

[9] XView - K051837

[12] Compound K051837

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Agnes M. Wang*

(Division Sign-Off)  
Division of Reproductive, Abdominal and  
Radiological Devices  
510(k) Number K081386

Prescription Use (Per 21 CFR 801.109)

# MyLab90 & 70XVG - CA631

| Mode of Operations                |             |             |             |     |               |                   |              |                              |                                  |             |                 |
|-----------------------------------|-------------|-------------|-------------|-----|---------------|-------------------|--------------|------------------------------|----------------------------------|-------------|-----------------|
| Clinical Application              | B           | M           | PWD         | CWD | Color Doppler | Amplitude Doppler | Combined [4] | Color Velocity Mapping (TVM) | Tissue Enhancement Imaging (TEI) | CnTI        | Other (specify) |
| Ophthalmic                        |             |             |             |     |               |                   |              |                              |                                  |             |                 |
| Fetal                             | P<br>Mtf369 | P<br>Mtf369 | P<br>Mtf369 |     | P<br>Mtf369   | P<br>Mtf369       | P<br>Mtf369  |                              | P<br>Mtf369                      | P<br>Mtf369 | 6, 8, 9         |
| Abdominal                         | P<br>Mtf369 | P<br>Mtf369 | P<br>Mtf369 |     | P<br>Mtf369   | P<br>Mtf369       | P<br>Mtf369  |                              | P<br>Mtf369                      | P<br>Mtf369 | 6, 8, 9         |
| Intraoperative (Abdominal)        |             |             |             |     |               |                   |              |                              |                                  |             |                 |
| Intraoperative Neurological       |             |             |             |     |               |                   |              |                              |                                  |             |                 |
| Pediatric                         | P<br>Mtf369 | P<br>Mtf369 | P<br>Mtf369 |     | P<br>Mtf369   | P<br>Mtf369       | P<br>Mtf369  |                              | P<br>Mtf369                      | P<br>Mtf369 |                 |
| Small Organ [1]                   |             |             |             |     |               |                   |              |                              |                                  |             |                 |
| Neonatal Cephalic                 |             |             |             |     |               |                   |              |                              |                                  |             |                 |
| Adult Cephalic                    |             |             |             |     |               |                   |              |                              |                                  |             |                 |
| Cardiac [2]                       |             |             |             |     |               |                   |              |                              |                                  |             |                 |
| Adult Cephalic                    |             |             |             |     |               |                   |              |                              |                                  |             |                 |
| Transesophageal (Non Cardiac)     |             |             |             |     |               |                   |              |                              |                                  |             |                 |
| Transrectal                       |             |             |             |     |               |                   |              |                              |                                  |             |                 |
| Transvaginal                      |             |             |             |     |               |                   |              |                              |                                  |             |                 |
| Transurethral                     |             |             |             |     |               |                   |              |                              |                                  |             |                 |
| Intravascular                     |             |             |             |     |               |                   |              |                              |                                  |             |                 |
| Peripheral Vascular               | P<br>Mtf369 | P<br>Mtf369 | P<br>Mtf369 |     | P<br>Mtf369   | P<br>Mtf369       | P<br>Mtf369  |                              | P<br>Mtf369                      | P<br>Mtf369 | 6, 8, 9         |
| Laparoscopic                      |             |             |             |     |               |                   |              |                              |                                  |             |                 |
| Musculo-skeletal Conventional [3] | P<br>Mtf369 | P<br>Mtf369 | P<br>Mtf369 |     | P<br>Mtf369   | P<br>Mtf369       | P<br>Mtf369  |                              | P<br>Mtf369                      | P<br>Mtf369 | 6, 8, 9         |
| Musculo-skeletal Superficial [3]  | P<br>Mtf369 | P<br>Mtf369 | P<br>Mtf369 |     | P<br>Mtf369   | P<br>Mtf369       | P<br>Mtf369  |                              | P<br>Mtf369                      | P<br>Mtf369 | 6, 8, 9         |
| Other (Urological)                | P<br>Mtf369 | P<br>Mtf369 | P<br>Mtf369 |     | P<br>Mtf369   | P<br>Mtf369       | P<br>Mtf369  |                              | P<br>Mtf369                      |             | 6, 8, 9         |

N = New; P = Previously Cleared by FDA

[3] Musculoskeletal - Nerve Block

[4] Combined modes

are: B+M+PW+CFM+PD

[6] 3D K051837

[8] VPan - MTF 374

[9] XView - K051837

Concurrence of CDRH, Office of Device Evaluation (ODE)

*[Signature]*

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number

K081386

Prescription Use (Per 21 CFR 801.109)

# MyLab90 & 70XVG - EC123

| Mode of Operations                |              |              |              |     |               |                   |              |                              |                                  |                        |
|-----------------------------------|--------------|--------------|--------------|-----|---------------|-------------------|--------------|------------------------------|----------------------------------|------------------------|
| Clinical Application              | B            | M            | PWD          | CWD | Color Doppler | Amplitude Doppler | Combined [4] | Color Velocity Mapping (TVM) | Tissue Enhancement Imaging (TEI) | Other (specify)        |
| Ophthalmic                        |              |              |              |     |               |                   |              |                              |                                  |                        |
| Fetal                             | P<br>K051837 | P<br>K051837 | P<br>K051837 |     | P<br>K051837  | P<br>K051837      | P<br>K051837 |                              | P<br>K051837                     | 6, 8, 9, 12<br>K051837 |
| Abdominal                         |              |              |              |     |               |                   |              |                              |                                  |                        |
| Intraoperative (Abdominal)        |              |              |              |     |               |                   |              |                              |                                  |                        |
| Intraoperative Neurological       |              |              |              |     |               |                   |              |                              |                                  |                        |
| Pediatric                         |              |              |              |     |               |                   |              |                              |                                  |                        |
| Small Organ [1]                   |              |              |              |     |               |                   |              |                              |                                  |                        |
| Neonatal Cephalic                 |              |              |              |     |               |                   |              |                              |                                  |                        |
| Adult Cephalic                    |              |              |              |     |               |                   |              |                              |                                  |                        |
| Cardiac [2]                       |              |              |              |     |               |                   |              |                              |                                  |                        |
| Adult Cephalic                    |              |              |              |     |               |                   |              |                              |                                  |                        |
| Transesophageal (Non Cardiac)     |              |              |              |     |               |                   |              |                              |                                  |                        |
| Transrectal                       | P<br>K051837 | P<br>K051837 | P<br>K051837 |     | P<br>K051837  | P<br>K051837      | P<br>K051837 |                              | P<br>K051837                     | 6, 8, 9, 12<br>K051837 |
| Transvaginal                      | P<br>K051837 | P<br>K051837 | P<br>K051837 |     | P<br>K051837  | P<br>K051837      | P<br>K051837 |                              | P<br>K051837                     | 6, 8, 9, 12<br>K051837 |
| Transurethral                     |              |              |              |     |               |                   |              |                              |                                  |                        |
| Intravascular                     |              |              |              |     |               |                   |              |                              |                                  |                        |
| Peripheral Vascular               |              |              |              |     |               |                   |              |                              |                                  |                        |
| Laparoscopic                      |              |              |              |     |               |                   |              |                              |                                  |                        |
| Musculo-skeletal Conventional [3] |              |              |              |     |               |                   |              |                              |                                  |                        |
| Musculo-skeletal Superficial [3]  |              |              |              |     |               |                   |              |                              |                                  |                        |
| Other (Urological)                | P<br>K051837 | P<br>K051837 | P<br>K051837 |     | P<br>K051837  | P<br>K051837      | P<br>K051837 |                              | P<br>K051837                     | 6, 8, 9, 12<br>K051837 |

N = New, P = Previously Cleared by FDA

[4] Combined modes are:

B+M+PW+CFM+PD

[6] 3D K051837

[8] VPan - MTF 374

[9] XView - K051837

[12] Compound - K051837

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Agg. M. W. Long*

(Division Sign-Off)  
Division of Reproductive, Abdominal and  
Radiological Devices  
510(k) Number K081386

Prescription Use (Per 21 CFR 801.109)

# MyLab90 & 70XVG - LA435

| Mode of Operations                |             |             |             |     |               |                   |              |                              |                                  |      |                 |
|-----------------------------------|-------------|-------------|-------------|-----|---------------|-------------------|--------------|------------------------------|----------------------------------|------|-----------------|
| Clinical Application              | B           | M           | PWD         | CWD | Color Doppler | Amplitude Doppler | Combined [4] | Color Velocity Mapping (TVM) | Tissue Enhancement Imaging (TEI) | CnTI | Other (specify) |
| Ophthalmic                        |             |             |             |     |               |                   |              |                              |                                  |      |                 |
| Fetal                             |             |             |             |     |               |                   |              |                              |                                  |      |                 |
| Abdominal                         |             |             |             |     |               |                   |              |                              |                                  |      |                 |
| Intraoperative (Abdominal)        |             |             |             |     |               |                   |              |                              |                                  |      |                 |
| Intraoperative Neurological       |             |             |             |     |               |                   |              |                              |                                  |      |                 |
| Pediatric                         | P<br>MTF329 | P<br>MTF329 | P<br>MTF329 |     | P<br>MTF329   | P<br>MTF329       | P<br>MTF329  |                              | P<br>MTF 329                     |      | 6, 8, 9, 13     |
| Small Organ [1]                   | P<br>MTF329 | P<br>MTF329 | P<br>MTF329 |     | P<br>MTF329   | P<br>MTF329       | P<br>MTF329  |                              | P<br>MTF 329                     |      | 6, 8, 9, 13     |
| Neonatal Cephalic                 |             |             |             |     |               |                   |              |                              |                                  |      |                 |
| Adult Cephalic                    |             |             |             |     |               |                   |              |                              |                                  |      |                 |
| Cardiac [2]                       |             |             |             |     |               |                   |              |                              |                                  |      |                 |
| Adult Cephalic                    |             |             |             |     |               |                   |              |                              |                                  |      |                 |
| Transesophageal (Non Cardiac)     |             |             |             |     |               |                   |              |                              |                                  |      |                 |
| Transrectal                       |             |             |             |     |               |                   |              |                              |                                  |      |                 |
| Transvaginal                      |             |             |             |     |               |                   |              |                              |                                  |      |                 |
| Transurethral                     |             |             |             |     |               |                   |              |                              |                                  |      |                 |
| Intravascular                     |             |             |             |     |               |                   |              |                              |                                  |      |                 |
| Peripheral Vascular               | P<br>MTF329 | P<br>MTF329 | P<br>MTF329 |     | P<br>MTF329   | P<br>MTF329       | P<br>MTF329  |                              | P<br>MTF 329                     |      | 6, 8, 9, 13     |
| Laparoscopic                      |             |             |             |     |               |                   |              |                              |                                  |      |                 |
| Musculo-skeletal Conventional [3] | P<br>MTF329 | P<br>MTF329 | P<br>MTF329 |     | P<br>MTF329   | P<br>MTF329       | P<br>MTF329  |                              | P<br>MTF 329                     |      | 6, 8, 9, 13     |
| Musculo-skeletal Superficial [3]  | P<br>MTF329 | P<br>MTF329 | P<br>MTF329 |     | P<br>MTF329   | P<br>MTF329       | P<br>MTF329  |                              | P<br>MTF 329                     |      | 6, 8, 9, 13     |
| Other (Urological)                |             |             |             |     |               |                   |              |                              |                                  |      |                 |

N = New; P = Previously Cleared by FDA

[1] Small Organs includes Breast, Thyroid and Testicles

[3] Musculoskeletal - Nerve Block

[4] Combined modes are:

B+M+PW+CFM+PD

[6] 3D MTF 374

[8] VPan - MTF 374

[9] XView - MTF329

[13] TP-View - MTF 374

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Joseph M. Whelan*

(Division Sign-Off)  
Division of Reproductive, Abdominal and  
Radiological Devices  
510(k) Number K081386

Prescription Use (Per 21 CFR 801.109)

# MyLab90 & 70XVG - LA522

| Mode of Operations                |              |              |              |     |               |                   |              |                              |                                  |              |                     |
|-----------------------------------|--------------|--------------|--------------|-----|---------------|-------------------|--------------|------------------------------|----------------------------------|--------------|---------------------|
| Clinical Application              | B            | M            | PWD          | CWD | Color Doppler | Amplitude Doppler | Combined [4] | Color Velocity Mapping (TVM) | Tissue Enhancement Imaging (TEI) | CnTI         | Other (specify)     |
| Ophthalmic                        |              |              |              |     |               |                   |              |                              |                                  |              |                     |
| Fetal                             |              |              |              |     |               |                   |              |                              |                                  |              |                     |
| Abdominal                         |              |              |              |     |               |                   |              |                              |                                  |              |                     |
| Intraoperative (Abdominal)        |              |              |              |     |               |                   |              |                              |                                  |              |                     |
| Intraoperative Neurological       |              |              |              |     |               |                   |              |                              |                                  |              |                     |
| Pediatric                         | P<br>K051837 | P<br>K051837 | P<br>K051837 |     | P<br>K051837  | P<br>K051837      | P<br>K051837 |                              | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12, 13     |
| Small Organ [1]                   | P<br>K051837 | P<br>K051837 | P<br>K051837 |     | P<br>K051837  | P<br>K051837      | P<br>K051837 |                              | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12, 13     |
| Neonatal Cephalic                 |              |              |              |     |               |                   |              |                              |                                  |              |                     |
| Adult Cephalic                    |              |              |              |     |               |                   |              |                              |                                  |              |                     |
| Cardiac [2]                       |              |              |              |     |               |                   |              |                              |                                  |              |                     |
| Adult Cephalic                    |              |              |              |     |               |                   |              |                              |                                  |              |                     |
| Transesophageal (Non Cardiac)     |              |              |              |     |               |                   |              |                              |                                  |              |                     |
| Transrectal                       |              |              |              |     |               |                   |              |                              |                                  |              |                     |
| Transvaginal                      |              |              |              |     |               |                   |              |                              |                                  |              |                     |
| Transurethral                     |              |              |              |     |               |                   |              |                              |                                  |              |                     |
| Intravascular                     |              |              |              |     |               |                   |              |                              |                                  |              |                     |
| Peripheral Vascular               | P<br>K051837 | P<br>K051837 | P<br>K051837 |     | P<br>K051837  | P<br>K051837      | P<br>K051837 |                              | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12, 13, 14 |
| Laparoscopic                      |              |              |              |     |               |                   |              |                              |                                  |              |                     |
| Musculo-skeletal Conventional [3] | P<br>K051837 | P<br>K051837 | P<br>K051837 |     | P<br>K051837  | P<br>K051837      | P<br>K051837 |                              | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12, 13     |
| Musculo-skeletal Superficial [3]  | P<br>K051837 | P<br>K051837 | P<br>K051837 |     | P<br>K051837  | P<br>K051837      | P<br>K051837 |                              | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12, 13     |
| Other (Urological)                |              |              |              |     |               |                   |              |                              |                                  |              |                     |

N = New; P = Previously Cleared by FDA

- [1] Small Organs includes Breast, Thyroid and Testicles  
 [2] Cardiac is Adult and Pediatric  
 [3] Musculoskeletal - Nerve Block  
 [4] Combined modes are:  
 B+M+PW+CFM+PD  
 [6] 3D - K060827 & MTF 369  
 [8] VPan - MTF 374  
 [9] XView - K051837  
 [12] Compound - K051837  
 [13] TP-View-MTF 374  
 [14] IMT -MTF 374

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)  
*[Signature]*

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number K081386

# MyLab90 & 70XVG - LA523

| Clinical Application              | Mode of Operations |              |              |     |               |                   |              |                              |                                  |              |                     |
|-----------------------------------|--------------------|--------------|--------------|-----|---------------|-------------------|--------------|------------------------------|----------------------------------|--------------|---------------------|
|                                   | B                  | M            | PWD          | CWD | Color Doppler | Amplitude Doppler | Combined [4] | Color Velocity Mapping (TVM) | Tissue Enhancement Imaging (TEI) | CnTI         | Other (Specify)     |
| Ophthalmic                        |                    |              |              |     |               |                   |              |                              |                                  |              |                     |
| Fetal                             |                    |              |              |     |               |                   |              |                              |                                  |              |                     |
| Abdominal                         |                    |              |              |     |               |                   |              |                              |                                  |              |                     |
| Intraoperative (Abdominal)        |                    |              |              |     |               |                   |              |                              |                                  |              |                     |
| Intraoperative Neurological       |                    |              |              |     |               |                   |              |                              |                                  |              |                     |
| Pediatric                         | P<br>K051837       | P<br>K051837 | P<br>K051837 |     | P<br>K051837  | P<br>K051837      | P<br>K051837 |                              | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12, 13     |
| Small Organ [1]                   | P<br>K051837       | P<br>K051837 | P<br>K051837 |     | P<br>K051837  | P<br>K051837      | P<br>K051837 |                              | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12, 13     |
| Neonatal Cephalic                 |                    |              |              |     |               |                   |              |                              |                                  |              |                     |
| Adult Cephalic                    |                    |              |              |     |               |                   |              |                              |                                  |              |                     |
| Cardiac [2]                       |                    |              |              |     |               |                   |              |                              |                                  |              |                     |
| Adult Cephalic                    |                    |              |              |     |               |                   |              |                              |                                  |              |                     |
| Transesophageal (Non Cardiac)     |                    |              |              |     |               |                   |              |                              |                                  |              |                     |
| Transrectal                       |                    |              |              |     |               |                   |              |                              |                                  |              |                     |
| Transvaginal                      |                    |              |              |     |               |                   |              |                              |                                  |              |                     |
| Transurethral                     |                    |              |              |     |               |                   |              |                              |                                  |              |                     |
| Intravascular                     |                    |              |              |     |               |                   |              |                              |                                  |              |                     |
| Peripheral Vascular               | P<br>K051837       | P<br>K051837 | P<br>K051837 |     | P<br>K051837  | P<br>K051837      | P<br>K051837 |                              | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12, 13, 14 |
| Laparoscopic                      |                    |              |              |     |               |                   |              |                              |                                  |              |                     |
| Musculo-skeletal Conventional [3] | P<br>K051837       | P<br>K051837 | P<br>K051837 |     | P<br>K051837  | P<br>K051837      | P<br>K051837 |                              | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12, 13     |
| Musculo-skeletal Superficial [3]  | P<br>K051837       | P<br>K051837 | P<br>K051837 |     | P<br>K051837  | P<br>K051837      | P<br>K051837 |                              | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12, 13     |
| Other (Urological)                |                    |              |              |     |               |                   |              |                              |                                  |              |                     |

N = New; P = Previously Cleared by FDA

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculoskeletal - Nerve Block

[4] Combined modes are:  
B+M+PW+CFM+PD

[6] 3D K051837

[8] VPan - MTF 374

[9] XView - K051837

[12] Compound - K051837

[13] TP-View - MTF 374

[14] IMT -MTF 374

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)  
*Joseph P. Wang*  
 Division of Reproductive, Abdominal and  
 Radiological Devices  
 510(k) Number K081386



# MyLab90 & 70XVG - LA532

|                                   | Mode of Operations |              |              |     |               |                   |              |                              |                                  |              |                 |
|-----------------------------------|--------------------|--------------|--------------|-----|---------------|-------------------|--------------|------------------------------|----------------------------------|--------------|-----------------|
| Clinical Application              | B                  | M            | PWD          | CWD | Color Doppler | Amplitude Doppler | Combined [4] | Color Velocity Mapping (TVM) | Tissue Enhancement Imaging (TEI) | CnTI         | Other (specify) |
| Ophthalmic                        |                    |              |              |     |               |                   |              |                              |                                  |              |                 |
| Fetal                             |                    |              |              |     |               |                   |              |                              |                                  |              |                 |
| Abdominal                         |                    |              |              |     |               |                   |              |                              |                                  |              |                 |
| Intraoperative (Abdominal)        |                    |              |              |     |               |                   |              |                              |                                  |              |                 |
| Intraoperative Neurological       |                    |              |              |     |               |                   |              |                              |                                  |              |                 |
| Pediatric                         | P<br>K051837       | P<br>K051837 | P<br>K051837 |     | P<br>K051837  | P<br>K051837      | P<br>K051837 |                              | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12, 13 |
| Small Organ [1]                   | P<br>K051837       | P<br>K051837 | P<br>K051837 |     | P<br>K051837  | P<br>K051837      | P<br>K051837 |                              | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12, 13 |
| Neonatal Cephalic                 |                    |              |              |     |               |                   |              |                              |                                  |              |                 |
| Adult Cephalic                    |                    |              |              |     |               |                   |              |                              |                                  |              |                 |
| Cardiac [2]                       |                    |              |              |     |               |                   |              |                              |                                  |              |                 |
| Adult Cephalic                    |                    |              |              |     |               |                   |              |                              |                                  |              |                 |
| Transesophageal (Non Cardiac)     |                    |              |              |     |               |                   |              |                              |                                  |              |                 |
| Transrectal                       |                    |              |              |     |               |                   |              |                              |                                  |              |                 |
| Transvaginal                      |                    |              |              |     |               |                   |              |                              |                                  |              |                 |
| Transurethral                     |                    |              |              |     |               |                   |              |                              |                                  |              |                 |
| Intravascular                     |                    |              |              |     |               |                   |              |                              |                                  |              |                 |
| Peripheral Vascular               | P<br>K051837       | P<br>K051837 | P<br>K051837 |     | P<br>K051837  | P<br>K051837      | P<br>K051837 |                              | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12, 13 |
| Laparoscopic                      |                    |              |              |     |               |                   |              |                              |                                  |              |                 |
| Musculo-skeletal Conventional [3] | P<br>MTF369        | P<br>MTF369  | P<br>MTF369  |     | P<br>MTF369   | P<br>MTF369       | P<br>MTF369  |                              | P<br>MTF369                      |              | 6, 8, 9, 12, 13 |
| Musculo-skeletal Superficial [3]  |                    |              |              |     |               |                   |              |                              |                                  |              |                 |
| Other (Urological)                |                    |              |              |     |               |                   |              |                              |                                  |              |                 |

N = New; P = Previously Cleared by FDA

- [1] Small Organs includes Breast, Thyroid and Testicles  
 [8] VPan - MTF 374  
 [9] XView - K051837  
 [3] Musculoskeletal - Nerve Block  
 [12] Compound - K051837  
 [4] Combined modes are:  
 B+M+PW+CFM+PD  
 [13] TP-View - MTF 374  
 [6] 3D K051837

Concurrence of CDRH, Office of Device Evaluation (ODE)

*[Signature]*

(Division Sign-Off)  
 Division of Reproductive, Abdominal and Radiological Devices  
 510(k) Number K081386

# MyLab90 & 70XVG-PA122

| Clinical Application              | Mode of Operations |              |              |              |               |                   |              |                              |                                  |              |                 |
|-----------------------------------|--------------------|--------------|--------------|--------------|---------------|-------------------|--------------|------------------------------|----------------------------------|--------------|-----------------|
|                                   | B                  | M            | PWD          | CWD          | Color Doppler | Amplitude Doppler | Combined [4] | Color Velocity Mapping [TVM] | Tissue Enhancement Imaging (TEI) | CnTI         | Other (Specify) |
| Ophthalmic                        |                    |              |              |              |               |                   |              |                              |                                  |              |                 |
| Fetal                             |                    |              |              |              |               |                   |              |                              |                                  |              |                 |
| Abdominal                         |                    |              |              |              |               |                   |              |                              |                                  |              |                 |
| Intraoperative (Abdominal)        |                    |              |              |              |               |                   |              |                              |                                  |              |                 |
| Intraoperative Neurological       |                    |              |              |              |               |                   |              |                              |                                  |              |                 |
| Pediatric                         | P<br>K051837       | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837  | P<br>K051837      | P<br>K051837 | P<br>K051837                 | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12     |
| Small Organ [1]                   |                    |              |              |              |               |                   |              |                              |                                  |              |                 |
| Neonatal Cephalic                 | P<br>K051837       | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837  | P<br>K051837      | P<br>K051837 | P<br>K051837                 | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12     |
| Adult Cephalic                    |                    |              |              |              |               |                   |              |                              |                                  |              |                 |
| Cardiac [2]                       | P<br>K051837       | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837  | P<br>K051837      | P<br>K051837 | P<br>K051837                 | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12     |
| Adult Cephalic                    |                    |              |              |              |               |                   |              |                              |                                  |              |                 |
| Transesophageal (Non Cardiac)     |                    |              |              |              |               |                   |              |                              |                                  |              |                 |
| Transrectal                       |                    |              |              |              |               |                   |              |                              |                                  |              |                 |
| Transvaginal                      |                    |              |              |              |               |                   |              |                              |                                  |              |                 |
| Transurethral                     |                    |              |              |              |               |                   |              |                              |                                  |              |                 |
| Intravascular                     |                    |              |              |              |               |                   |              |                              |                                  |              |                 |
| Peripheral Vascular               | P<br>K051837       | P<br>K051837 | P<br>K051837 | P<br>K051837 | P<br>K051837  | P<br>K051837      | P<br>K051837 | P<br>K051837                 | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12     |
| Laparoscopic                      |                    |              |              |              |               |                   |              |                              |                                  |              |                 |
| Musculo-skeletal Conventional [3] |                    |              |              |              |               |                   |              |                              |                                  |              |                 |
| Musculo-skeletal Superficial [3]  |                    |              |              |              |               |                   |              |                              |                                  |              |                 |
| Other (Urological)                |                    |              |              |              |               |                   |              |                              |                                  |              |                 |

N = New; P = Previously Cleared by FDA

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculoskeletal - Nerve Block

[4] Combined modes are:

B+M+PW+CW+CFM+PD

[6] 3D K060827 & MTF 36:

[8] VPan MTF 374

[9] XView K051837

[12] Compound K051837

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number

K051386

# MyLab90 & XVG - PA230

|                                   |              | Mode of Operations |              |              |               |                   |              |                              |                                  |              |                 |
|-----------------------------------|--------------|--------------------|--------------|--------------|---------------|-------------------|--------------|------------------------------|----------------------------------|--------------|-----------------|
| Clinical Application              | B            | M                  | PWD          | CWD          | Color Doppler | Amplitude Doppler | Combined [4] | Color Velocity Mapping (TVM) | Tissue Enhancement Imaging (TEI) | CnTi         | Other (specify) |
| Ophthalmic                        |              |                    |              |              |               |                   |              |                              |                                  |              |                 |
| Fetal                             |              |                    |              |              |               |                   |              |                              |                                  |              |                 |
| Abdominal                         | P<br>K051837 | P<br>K051837       | P<br>K051837 | P<br>K051837 | P<br>K051837  | P<br>K051837      | P<br>K051837 | P<br>K051837                 | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12     |
| Intraoperative (Abdominal)        |              |                    |              |              |               |                   |              |                              |                                  |              |                 |
| Intraoperative Neurological       |              |                    |              |              |               |                   |              |                              |                                  |              |                 |
| Pediatric                         |              |                    |              |              |               |                   |              |                              |                                  |              |                 |
| Small Organ [1]                   |              |                    |              |              |               |                   |              |                              |                                  |              |                 |
| Neonatal Cephalic                 |              |                    |              |              |               |                   |              |                              |                                  |              |                 |
| Adult Cephalic                    | P<br>K051837 | P<br>K051837       | P<br>K051837 | P<br>K051837 | P<br>K051837  | P<br>K051837      | P<br>K051837 | P<br>K051837                 | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12     |
| Cardiac [2]                       | P<br>K051837 | P<br>K051837       | P<br>K051837 | P<br>K051837 | P<br>K051837  | P<br>K051837      | P<br>K051837 | P<br>K051837                 | P<br>K051837                     | P<br>K051837 | 6, 8, 9, 12     |
| Adult Cephalic                    |              |                    |              |              |               |                   |              |                              |                                  |              |                 |
| Transesophageal (Non Cardiac)     |              |                    |              |              |               |                   |              |                              |                                  |              |                 |
| Transrectal                       |              |                    |              |              |               |                   |              |                              |                                  |              |                 |
| Transvaginal                      |              |                    |              |              |               |                   |              |                              |                                  |              |                 |
| Transurethral                     |              |                    |              |              |               |                   |              |                              |                                  |              |                 |
| Intravascular                     |              |                    |              |              |               |                   |              |                              |                                  |              |                 |
| Peripheral Vascular               | P<br>MTF369  | P<br>MTF369        | P<br>MTF369  | P<br>MTF369  | P<br>MTF369   | P<br>MTF369       | P<br>MTF369  | P<br>MTF369                  | P<br>MTF369                      | P<br>MTF369  | 6, 8, 9, 12     |
| Laparoscopic                      |              |                    |              |              |               |                   |              |                              |                                  |              |                 |
| Musculo-skeletal Conventional [3] |              |                    |              |              |               |                   |              |                              |                                  |              |                 |
| Musculo-skeletal Superficial [3]  |              |                    |              |              |               |                   |              |                              |                                  |              |                 |
| Other (Urological)                |              |                    |              |              |               |                   |              |                              |                                  |              |                 |

N = New; P = Previously Cleared by FDA

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculoskeletal - Nerve Block

[4] Combined modes are:

B+M+PW+CW+CFM+PD

[6] 3D K060827 & MTF 369

[8] VPan MTF 374

[9] XView K051837

[12] Compound K051837

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Joseph M. Wang*

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number K081386

Prescription Use (Per 21 CFR 801.109)

# MyLab70

| Clinical Application              | Mode of Operations |         |         |         |               |                        |              |   |   |                       | Other (Specify)           |
|-----------------------------------|--------------------|---------|---------|---------|---------------|------------------------|--------------|---|---|-----------------------|---------------------------|
|                                   | B                  | M       | PWD     | CWD     | Color Doppler | Amplitude Doppler (PD) | Combined (4) | Color Velocity Mapping (TVM) K052805 & MTF323 | Tissue Enhancement Imaging (TEI) MTF323 | CnTI K052805 & MTF323 |                           |
| Ophthalmic                        |                    |         |         |         |               |                        |              |   |   |                       |                           |
| Fetal                             | P                  | P       | P       | P       | P             | P                      | P            | P   | P                                       | P                     | 5, 6, 7, 8, 9, 12         |
|                                   | K051308            | K051308 | K051308 | K051308 | K051308       | K051308                | K051308      | K051308                                       | K051308                                 | K052805               |                           |
| Abdominal                         | P                  | P       | P       | P       | P             | P                      | P            | P   | P                                       | P                     | 5, 6, 7, 8, 9, 12, 13     |
|                                   | K051308            | K051308 | K051308 | K051308 | K051308       | K051308                | K051308      | K051308                                       | K051308                                 | K052805               |                           |
| Intraoperative (Abdominal)        | P                  | P       | P       | P       | P             | P                      | P            | P   | P                                       | P                     | 6, 8, 9, 12, 13           |
|                                   | K052805            | K052805 | K052805 | K052805 | K052805       | K052805                | K052805      | K052805                                       | K052805                                 | K052805               |                           |
| Intraoperative Neurological       |                    |         |         |         |               |                        |              |   |   |                       |                           |
| Pediatric                         | P                  | P       | P       | P       | P             | P                      | P            | P   | P                                       | P                     | 5, 6, 7, 8, 9, 12, 13     |
|                                   | K051308            | K051308 | K051308 | K051308 | K051308       | K051308                | K051308      | K051308                                       | K051308                                 | K052805               |                           |
| Small Organ [1]                   | P                  | P       | P       | P       | P             | P                      | P            | P   | P                                       | P                     | 5, 6, 7, 8, 9, 12, 13     |
|                                   | K051308            | K051308 | K051308 | K051308 | K051308       | K051308                | K051308      | K051308                                       | K051308                                 | K052805               |                           |
| Neonatal Cephalic                 | P                  | P       | P       | P       | P             | P                      | P            | P   | P                                       | P                     | 5, 6, 8, 9, 12            |
|                                   | K051308            | K051308 | K051308 | K051308 | K051308       | K051308                | K051308      | K051308                                       | K051308                                 | K052805               |                           |
| Adult Cephalic (MTF346)           | P                  | P       | P       | P       | P             | P                      | P            | P   | P                                       | P                     | 5, 6, 9, 12               |
|                                   | K051308            | K051308 | K051308 | K051308 | K051308       | K051308                | K051308      | K051308                                       | K051308                                 | K052805               |                           |
| Cardiac [2] (MTF356)              | P                  | P       | P       | P       | P             | P                      | P            | P   | P                                       | P                     | 5, 6, 7, 8, 9, 12         |
|                                   | K051308            | K051308 | K051308 | K051308 | K051308       | K051308                | K051308      | K051308                                       | K051308                                 | K052805               |                           |
| Transesophageal (Cardiac)         | P                  | P       | P       | P       | P             | P                      | P            | P   | P                                       | P                     | 5, 6, 9, 12               |
|                                   | K051308            | K051308 | K051308 | K051308 | K051308       | K051308                | K051308      | K051308                                       | K051308                                 | K052805               |                           |
| Transesophageal (Non Cardiac)     | P                  | P       | P       | P       | P             | P                      | P            | P   | P                                       | P                     | 5, 6, 8, 9, 12, 13        |
|                                   | K051308            | K051308 | K051308 | K051308 | K051308       | K051308                | K051308      | K051308                                       | K051308                                 | K052805               |                           |
| Transrectal                       | P                  | P       | P       | P       | P             | P                      | P            | P   | P                                       | P                     | 5, 6, 8, 9, 12            |
|                                   | K051308            | K051308 | K051308 | K051308 | K051308       | K051308                | K051308      | K051308                                       | K051308                                 | K052805               |                           |
| Transvaginal                      | P                  | P       | P       | P       | P             | P                      | P            | P   | P                                       | P                     | 5, 6, 8, 9, 12            |
|                                   | K051308            | K051308 | K051308 | K051308 | K051308       | K051308                | K051308      | K051308                                       | K051308                                 | K052805               |                           |
| Transurethral                     |                    |         |         |         |               |                        |              |   |   |                       |                           |
| Intravascular                     | P                  | P       | P       | P       | P             | P                      | P            | P   | P                                       | P                     | 5, 6, 7, 8, 9, 12, 13, 14 |
| Peripheral Vascular               | K051308            | K051308 | K051308 | K051308 | K051308       | K051308                | K051308      | K051308                                       | K051308                                 | K052805               |                           |
| Laparoscopic                      |                    |         |         |         |               |                        |              |   |   |                       |                           |
| Musculo-skeletal Conventional [3] | P                  | P       | P       | P       | P             | P                      | P            | P   | P                                       | P                     | 5, 6, 7, 8, 9, 12, 13     |
|                                   | K051308            | K051308 | K051308 | K051308 | K051308       | K051308                | K051308      | K051308                                       | K051308                                 | K052805               |                           |
| Musculo-skeletal Supercut [3]     | P                  | P       | P       | P       | P             | P                      | P            | P   | P                                       | P                     | 5, 6, 7, 8, 9, 12, 13     |
|                                   | K051308            | K051308 | K051308 | K051308 | K051308       | K051308                | K051308      | K051308                                       | K051308                                 | K052805               |                           |
| Other (Urological)                | P                  | P       | P       | P       | P             | P                      | P            | P   | P                                       | P                     | 5, 6, 7, 8, 9, 12, 13     |
|                                   | K051308            | K051308 | K051308 | K051308 | K051308       | K051308                | K051308      | K051308                                       | K051308                                 | K052805               |                           |

N = New; P = Previously Cleared by FDA

- [1] Small Organs includes Breast, Thyroid and Cardiac is Adult and Pediatric
- [2] Cardiac is Adult and Pediatric
- [3] Musculo Skeletal - Nerve Block- k071996
- [4] Combined modes are: B+M+PW+CW+CFM+PD
- [5] CMM K052805

- [6] 3D K060827
- [7] 4D K060827 MTF356
- [8] VPAN K052805, MTF323 & 374
- [9] XView MTF336
- [10] Stress K051308

- [11] Xstrain K060827
- [12] Compound Imaging - K052805
- [13] TP-View - MTF#374
- [14] IMT - MTF#331 & 374
- [15] Automatic Gain - MTF#374

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)  
  
 Division of Reproductive, Abdominal and Radiological Devices  
 510(k) Number K081386

| Clinical Application              | Mode of Operations |              |              |     |               |                   |              |                              |                                  |             | Other (specify) |
|-----------------------------------|--------------------|--------------|--------------|-----|---------------|-------------------|--------------|------------------------------|----------------------------------|-------------|-----------------|
|                                   | B                  | M            | PWD          | CWD | Color Doppler | Amplitude Doppler | Combined [4] | Color Velocity Mapping (TVM) | Tissue Enhancement Imaging (TEI) | Cn71        |                 |
| Ophthalmic                        |                    |              |              |     |               |                   |              |                              |                                  |             |                 |
| Fetal                             | P<br>K051308       | P<br>K051308 | P<br>K051308 |     | P<br>K051308  | P<br>K051308      | P<br>K051308 | P<br>MTF323                  | P<br>K051308                     | P<br>MTF323 | 6, 8, 9         |
| Abdominal                         | P<br>K051308       | P<br>K051308 | P<br>K051308 |     | P<br>K051308  | P<br>K051308      | P<br>K051308 | P<br>MTF323                  | P<br>K051308                     | P<br>MTF323 | 6, 8, 9         |
| Intraoperative (Abdominal)        |                    |              |              |     |               |                   |              |                              |                                  |             |                 |
| Intraoperative Neurological       |                    |              |              |     |               |                   |              |                              |                                  |             |                 |
| Pediatric                         | P<br>K051308       | P<br>K051308 | P<br>K051308 |     | P<br>K051308  | P<br>K051308      | P<br>K051308 | P<br>MTF323                  | P<br>K051308                     | P<br>MTF323 | 6, 8, 9         |
| Small Organ [1]                   |                    |              |              |     |               |                   |              |                              |                                  |             |                 |
| Neonatal Cephalic                 |                    |              |              |     |               |                   |              |                              |                                  |             |                 |
| Adult Cephalic                    |                    |              |              |     |               |                   |              |                              |                                  |             |                 |
| Cardiac [2]                       |                    |              |              |     |               |                   |              |                              |                                  |             |                 |
| Transesophageal (Cardiac)         |                    |              |              |     |               |                   |              |                              |                                  |             |                 |
| Transesophageal (Non Cardiac)     |                    |              |              |     |               |                   |              |                              |                                  |             |                 |
| Transrectal                       |                    |              |              |     |               |                   |              |                              |                                  |             |                 |
| Transvaginal                      |                    |              |              |     |               |                   |              |                              |                                  |             |                 |
| Transurethral                     |                    |              |              |     |               |                   |              |                              |                                  |             |                 |
| Intravascular                     |                    |              |              |     |               |                   |              |                              |                                  |             |                 |
| Peripheral Vascular               | P<br>K051308       | P<br>K051308 | P<br>K051308 |     | P<br>K051308  | P<br>K051308      | P<br>K051308 | P<br>MTF323                  | P<br>K051308                     | P<br>MTF323 | 6, 8, 9         |
| Laparoscopic                      |                    |              |              |     |               |                   |              |                              |                                  |             |                 |
| Musculo-skeletal Conventional [3] | P<br>MTF356        | P<br>MTF356  | P<br>MTF356  |     | P<br>MTF356   | P<br>MTF356       | P<br>MTF356  |                              | P<br>MTF356                      |             | 6, 8, 9         |
| Musculo-skeletal Superficial [3]  | P<br>MTF356        | P<br>MTF356  | P<br>MTF356  |     | P<br>MTF356   | P<br>MTF356       | P<br>MTF356  |                              | P<br>MTF356                      |             | 6, 8, 9         |
| Other (Urological)                | P<br>K051308       | P<br>K051308 | P<br>K051308 |     | P<br>K051308  | P<br>K051308      | P<br>K051308 | P<br>MTF323                  | P<br>K051308                     | P<br>MTF323 | 6, 8, 9         |

N = New; P = Previously Cleared by FDA

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are:

B+M+PW+CFM+PD

[6] 3D - MTF 356

[8] VPan - MTF 323

[9] XView - MTF 336

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number K081386

# 70 - CA430

| Mode of Operations                |              |              |              |     |               |                   |              |                              |                                  |              |                 |
|-----------------------------------|--------------|--------------|--------------|-----|---------------|-------------------|--------------|------------------------------|----------------------------------|--------------|-----------------|
| Clinical Application              | B            | M            | PWD          | CWD | Color Doppler | Amplitude Doppler | Combined [4] | Color Velocity Mapping (TVM) | Tissue Enhancement Imaging (TEI) | CnTI         | Other (specify) |
| Ophthalmic                        |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Fetal                             | P<br>K051308 | P<br>K051308 | P<br>K051308 |     | P<br>K051308  | P<br>K051308      | P<br>K051308 |                              | P<br>K051308                     |              | 6, 8, 9         |
| Abdominal                         | P<br>K051308 | P<br>K051308 | P<br>K051308 |     | P<br>K051308  | P<br>K051308      | P<br>K051308 |                              | P<br>K051308                     | P<br>MTF 323 | 6, 8, 9         |
| Intraoperative (Abdominal)        |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Intraoperative Neurological       |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Pediatric                         | P<br>MTF347  | P<br>MTF347  | P<br>MTF347  |     | P<br>MTF347   | P<br>MTF347       | P<br>MTF347  |                              | P<br>MTF347                      |              | 6, 8, 9         |
| Small Organ [1]                   |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Neonatal Cephalic                 |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Adult Cephalic                    |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Cardiac [2]                       |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Transesophageal (Cardiac)         |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Transesophageal (Non Cardiac)     |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Transrectal                       |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Transvaginal                      |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Transurethral                     |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Intravascular                     |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Peripheral Vascular               | P<br>K051308 | P<br>K051308 | P<br>K051308 |     | P<br>K051308  | P<br>K051308      | P<br>K051308 |                              | P<br>K051308                     | P<br>MTF323  | 6, 8, 9         |
| Laparoscopic                      |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Musculo-skeletal Conventional [3] |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Musculo-skeletal Superficial [3]  |              |              |              |     |               |                   |              |                              |                                  |              |                 |
| Other (Urological)                | P<br>MTF347  | P<br>MTF347  | P<br>MTF347  |     | P<br>MTF347   | P<br>MTF347       | P<br>MTF347  |                              | P<br>MTF347                      |              | 6, 8, 9         |

N = New; P = Previously Cleared by FDA

[4] Combined modes are:

B+M+PW+CFM+PD

[6] 3D - MTF 356

[8] VPan - MTF 323

[9] XView - MTF 336

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

Prescription Use (Per 21 CFR 801.109)

510(k) Number

K081386

*Appt M Wdy*

| Clinical Application              | Mode of Operations |             |             |     |               |                   |              |                              |                                  |             |                 |
|-----------------------------------|--------------------|-------------|-------------|-----|---------------|-------------------|--------------|------------------------------|----------------------------------|-------------|-----------------|
|                                   | B                  | M           | PWD         | CWD | Color Doppler | Amplitude Doppler | Combined [4] | Color Velocity Mapping (TVM) | Tissue Enhancement Imaging (TEI) | CnTI        | Other (specify) |
| Ophthalmic                        |                    |             |             |     |               |                   |              |                              |                                  |             |                 |
| Fetal                             | P<br>MTF329        | P<br>MTF329 | P<br>MTF329 |     | P<br>MTF329   | P<br>MTF329       | P<br>MTF329  |                              | P<br>MTF329                      | P<br>MTF346 | 6, 8, 9         |
| Abdominal                         | P<br>MTF329        | P<br>MTF329 | P<br>MTF329 |     | P<br>MTF329   | P<br>MTF329       | P<br>MTF329  |                              | P<br>MTF329                      | P<br>MTF346 | 6, 8, 9         |
| Intraoperative (Abdominal)        |                    |             |             |     |               |                   |              |                              |                                  |             |                 |
| Intraoperative Neurological       |                    |             |             |     |               |                   |              |                              |                                  |             |                 |
| Pediatric                         |                    |             |             |     |               |                   |              |                              |                                  |             |                 |
| Small Organ [1]                   | P<br>MTF329        | P<br>MTF329 | P<br>MTF329 |     | P<br>MTF329   | P<br>MTF329       | P<br>MTF329  |                              | P<br>MTF329                      | P<br>MTF346 | 6, 8, 9         |
| Neonatal Cephalic                 |                    |             |             |     |               |                   |              |                              |                                  |             |                 |
| Adult Cephalic                    |                    |             |             |     |               |                   |              |                              |                                  |             |                 |
| Cardiac [2]                       |                    |             |             |     |               |                   |              |                              |                                  |             |                 |
| Transesophageal (Cardiac)         |                    |             |             |     |               |                   |              |                              |                                  |             |                 |
| Transesophageal (Non Cardiac)     |                    |             |             |     |               |                   |              |                              |                                  |             |                 |
| Transrectal                       |                    |             |             |     |               |                   |              |                              |                                  |             |                 |
| Transvaginal                      |                    |             |             |     |               |                   |              |                              |                                  |             |                 |
| Transurethral                     |                    |             |             |     |               |                   |              |                              |                                  |             |                 |
| Intravascular                     |                    |             |             |     |               |                   |              |                              |                                  |             |                 |
| Peripheral Vascular               | P<br>MTF329        | P<br>MTF329 | P<br>MTF329 |     | P<br>MTF329   | P<br>MTF329       | P<br>MTF329  |                              | P<br>MTF329                      | P<br>MTF346 | 6, 8, 9         |
| Laparoscopic                      |                    |             |             |     |               |                   |              |                              |                                  |             |                 |
| Musculo-skeletal Conventional [3] |                    |             |             |     |               |                   |              |                              |                                  |             |                 |
| Musculo-skeletal Superficial [3]  |                    |             |             |     |               |                   |              |                              |                                  |             |                 |
| Other (Urological)                | P<br>MTF329        | P<br>MTF329 | P<br>MTF329 |     | P<br>MTF329   | P<br>MTF329       | P<br>MTF329  |                              | P<br>MTF329                      | P<br>MTF346 | 6, 8, 9         |

N = New; P = Previously Cleared by FDA

[4] Combined modes are:

B+M+PW+CFM+PD

[6] 3D - MTF 356

[8] VPan - MTF 323

[9] XView - MTF 336

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number K081386

# 70 - CA621

| Mode of Operations                |              |              |              |     |               |                   |              |                              |                                  |             |                 |
|-----------------------------------|--------------|--------------|--------------|-----|---------------|-------------------|--------------|------------------------------|----------------------------------|-------------|-----------------|
| Clinical Application              | B            | M            | PWD          | CWD | Color Doppler | Amplitude Doppler | Combined [4] | Color Velocity Mapping (TVM) | Tissue Enhancement Imaging (TEI) | CnTI        | Other (specify) |
| Ophthalmic                        |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Fetal                             | P<br>K051308 | P<br>K051308 | P<br>K051308 |     | P<br>K051308  | P<br>K051308      | P<br>K051308 | P<br>Mtf323                  | P<br>K051308                     | P<br>Mtf323 | 6, 8, 9         |
| Abdominal                         | P<br>K051308 | P<br>K051308 | P<br>K051308 |     | P<br>K051308  | P<br>K051308      | P<br>K051308 | P<br>Mtf323                  | P<br>K051308                     | P<br>Mtf323 | 6, 8, 9         |
| Intraoperative (Abdominal)        |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Intraoperative Neurological       |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Pediatric                         | P<br>Mtf347  | P<br>Mtf347  | P<br>Mtf347  |     | P<br>Mtf347   | P<br>Mtf347       | P<br>Mtf347  |                              | P<br>Mtf347                      |             | 6, 8, 9         |
| Small Organ [1]                   |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Neonatal Cephalic                 |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Adult Cephalic                    |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Cardiac [2]                       |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Transesophageal (Cardiac)         |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Transesophageal (Non Cardiac)     |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Transrectal                       |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Transvaginal                      |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Transurethral                     |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Intravascular                     |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Peripheral Vascular               | P<br>K051308 | P<br>K051308 | P<br>K051308 |     | P<br>K051308  | P<br>K051308      | P<br>K051308 | P<br>Mtf323                  | P<br>K051308                     | P<br>Mtf323 | 6, 8, 9         |
| Laparoscopic                      |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Musculo-skeletal Conventional [3] |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Musculo-skeletal Superficial [3]  |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Other (Urological)                | P<br>K051308 | P<br>K051308 | P<br>K051308 |     | P<br>K051308  | P<br>K051308      | P<br>K051308 | P<br>Mtf323                  | P<br>K051308                     | P<br>Mtf323 | 6, 8, 9         |

N = New; P = Previously Cleared by FDA

[4] Combined modes are:

B+M+PW+CFM+PD

[6] 3D - MTF 356

[8] VPan - MTF 323

[9] XView - MTF 336

Concurrence of CDRH, Office of Device Evaluation (ODE)

*[Signature]*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal and  
 Radiological Devices  
 510(k) Number K081386

Prescription Use (Per 21 CFR 801.109)



# 70 - CA631

| Mode of Operations                |        |        |        |     |               |                   |              |                              |                                  |      |                 |
|-----------------------------------|--------|--------|--------|-----|---------------|-------------------|--------------|------------------------------|----------------------------------|------|-----------------|
| Clinical Application              | B      | M      | PWD    | CWD | Color Doppler | Amplitude Doppler | Combined [4] | Color Velocity Mapping (TVM) | Tissue Enhancement Imaging (TEI) | CnTI | Other (specify) |
| Ophthalmic                        |        |        |        |     |               |                   |              |                              |                                  |      |                 |
| Fetal                             | P      | P      | P      |     | P             | P                 | P            |                              | P                                |      | 6, 8, 9         |
|                                   | MTF356 | MTF356 | MTF356 |     | MTF356        | MTF356            | MTF356       |                              | MTF356                           |      |                 |
| Abdominal                         | P      | P      | P      |     | P             | P                 | P            |                              | P                                |      | 6, 8, 9         |
|                                   | MTF356 | MTF356 | MTF356 |     | MTF356        | MTF356            | MTF356       |                              | MTF356                           |      |                 |
| Intraoperative (Abdominal)        |        |        |        |     |               |                   |              |                              |                                  |      |                 |
| Intraoperative Neurological       |        |        |        |     |               |                   |              |                              |                                  |      |                 |
| Pediatric                         |        |        |        |     |               |                   |              |                              |                                  |      |                 |
| Small Organ [1]                   |        |        |        |     |               |                   |              |                              |                                  |      |                 |
| Neonatal Cephalic                 |        |        |        |     |               |                   |              |                              |                                  |      |                 |
| Adult Cephalic                    |        |        |        |     |               |                   |              |                              |                                  |      |                 |
| Cardiac [2]                       |        |        |        |     |               |                   |              |                              |                                  |      |                 |
| Transesophageal (Cardiac)         |        |        |        |     |               |                   |              |                              |                                  |      |                 |
| Transesophageal (Non Cardiac)     |        |        |        |     |               |                   |              |                              |                                  |      |                 |
| Transrectal                       |        |        |        |     |               |                   |              |                              |                                  |      |                 |
| Transvaginal                      |        |        |        |     |               |                   |              |                              |                                  |      |                 |
| Transurethral                     |        |        |        |     |               |                   |              |                              |                                  |      |                 |
| Intravascular                     |        |        |        |     |               |                   |              |                              |                                  |      |                 |
| Peripheral Vascular               | P      | P      | P      |     | P             | P                 | P            |                              | P                                |      | 6, 8, 9         |
|                                   | MTF356 | MTF356 | MTF356 |     | MTF356        | MTF356            | MTF356       |                              | MTF356                           |      |                 |
| Laparoscopic                      |        |        |        |     |               |                   |              |                              |                                  |      |                 |
| Musculo-skeletal Conventional [3] |        |        |        |     |               |                   |              |                              |                                  |      |                 |
| Musculo-skeletal Superficial [3]  |        |        |        |     |               |                   |              |                              |                                  |      |                 |
| Other (Urological)                | P      | P      | P      |     | P             | P                 | P            |                              | P                                |      | 6, 8, 9         |
|                                   | MTF356 | MTF356 | MTF356 |     | MTF356        | MTF356            | MTF356       |                              | MTF356                           |      |                 |

N = New; P = Previously Cleared by FDA

[4] Combined modes are:

B+M+PW+CFM+PD

[6] 3D - MTF 356

[8] VPan - MTF 356

[9] XView - MTF 356

Concurrence of CDRH, Office of Device Evaluation (ODE)

*[Signature]*

(Division Sign-Off)  
Division of Reproductive, Abdominal and  
Radiological Devices K081386  
510(k) Number

# 70 - EC123

| Mode of Operations                |              |              |              |     |               |                   |              |                              |                                  |             |                 |
|-----------------------------------|--------------|--------------|--------------|-----|---------------|-------------------|--------------|------------------------------|----------------------------------|-------------|-----------------|
| Clinical Application              | B            | M            | PWD          | CWD | Color Doppler | Amplitude Doppler | Combined [4] | Color Velocity Mapping (TVM) | Tissue Enhancement Imaging (TEI) | CnTI        | Other (specify) |
| Ophthalmic                        |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Fetal                             | P<br>K051308 | P<br>K051308 | P<br>K051308 |     | P<br>K051308  | P<br>K051308      | P<br>K051308 | P<br>Mtf323                  | P<br>K051308                     | P<br>Mtf323 | 6, 8, 9         |
| Abdominal                         |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Intraoperative (Abdominal)        |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Intraoperative Neurological       |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Pediatric                         |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Small Organ [1]                   |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Neonatal Cephalic                 |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Adult Cephalic                    |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Cardiac [2]                       |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Transesophageal (Cardiac)         |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Transesophageal (Non Cardiac)     |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Transrectal                       | P<br>K051308 | P<br>K051308 | P<br>K051308 |     | P<br>K051308  | P<br>K051308      | P<br>K051308 | P<br>Mtf323                  | P<br>K051308                     | P<br>Mtf323 | 6, 8, 9         |
| Transvaginal                      | P<br>K051308 | P<br>K051308 | P<br>K051308 |     | P<br>K051308  | P<br>K051308      | P<br>K051308 | P<br>Mtf323                  | P<br>K051308                     | P<br>Mtf323 | 6, 8, 9         |
| Transurethral                     |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Intravascular                     |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Peripheral Vascular               |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Laparoscopic                      |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Musculo-skeletal Conventional [3] |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Musculo-skeletal Superficial [3]  |              |              |              |     |               |                   |              |                              |                                  |             |                 |
| Other (Urological)                | P<br>K051308 | P<br>K051308 | P<br>K051308 |     | P<br>K051308  | P<br>K051308      | P<br>K051308 | P<br>Mtf323                  | P<br>K051308                     | P<br>Mtf323 | 6, 8, 9         |

N = New; P = Previously Cleared by FDA

[4] Combined modes are:

B+M+PW+CFM+PD

[6] 3D - MTF 356

[8] VPan - MTF 323

[9] XView - MTF 336

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) *Joseph M. Whelan*

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number *K081386*

Prescription Use (Per 21 CFR 801.109)

70-LA435

| Mode of Operations                |        |        |        |     |               |                   |              |                              |                                  |      |                 |
|-----------------------------------|--------|--------|--------|-----|---------------|-------------------|--------------|------------------------------|----------------------------------|------|-----------------|
| Clinical Application              | B      | M      | PWD    | CWD | Color Doppler | Amplitude Doppler | Combined [4] | Color Velocity Mapping (TVM) | Tissue Enhancement Imaging (TEI) | CnTI | Other (specify) |
| Ophthalmic                        |        |        |        |     |               |                   |              |                              |                                  |      |                 |
| Fetal                             |        |        |        |     |               |                   |              |                              |                                  |      |                 |
| Abdominal                         |        |        |        |     |               |                   |              |                              |                                  |      |                 |
| Intraoperative (Abdominal)        |        |        |        |     |               |                   |              |                              |                                  |      |                 |
| Intraoperative Neurological       |        |        |        |     |               |                   |              |                              |                                  |      |                 |
| Pediatric                         |        |        |        |     |               |                   |              |                              |                                  |      |                 |
|                                   | P      | P      | P      |     | P             | P                 | P            |                              | P                                |      | 6, 8, 9, 13     |
| Small Organ [1]                   | MtF329 | MtF329 | MtF329 |     | MtF329        | MtF329            | MtF329       |                              | MtF 329                          |      |                 |
|                                   | P      | P      | P      |     | P             | P                 | P            |                              | P                                |      | 6, 8, 9, 13     |
|                                   | MtF329 | MtF329 | MtF329 |     | MtF329        | MtF329            | MtF329       |                              |                                  |      |                 |
| Neonatal Cephalic                 |        |        |        |     |               |                   |              |                              |                                  |      |                 |
| Adult Cephalic                    |        |        |        |     |               |                   |              |                              |                                  |      |                 |
| Cardiac [2]                       |        |        |        |     |               |                   |              |                              |                                  |      |                 |
| Transesophageal (Cardiac)         |        |        |        |     |               |                   |              |                              |                                  |      |                 |
| Transesophageal (Non Cardiac)     |        |        |        |     |               |                   |              |                              |                                  |      |                 |
| Transrectal                       |        |        |        |     |               |                   |              |                              |                                  |      |                 |
| Transvaginal                      |        |        |        |     |               |                   |              |                              |                                  |      |                 |
| Transurethral                     |        |        |        |     |               |                   |              |                              |                                  |      |                 |
| Intravascular                     |        |        |        |     |               |                   |              |                              |                                  |      |                 |
| Peripheral Vascular               | P      | P      | P      |     | P             | P                 | P            |                              | P                                |      | 6, 8, 9, 13     |
|                                   | MtF329 | MtF329 | MtF329 |     | MtF329        | MtF329            | MtF329       |                              | MtF 329                          |      |                 |
| Laparoscopic                      |        |        |        |     |               |                   |              |                              |                                  |      |                 |
| Musculo-skeletal Conventional [3] | P      | P      | P      |     | P             | P                 | P            |                              | P                                |      | 6, 8, 9, 13     |
|                                   | MtF329 | MtF329 | MtF329 |     | MtF329        | MtF329            | MtF329       |                              | MtF 329                          |      |                 |
| Musculo-skeletal Superficial [3]  | P      | P      | P      |     | P             | P                 | P            |                              | P                                |      | 6, 8, 9, 13     |
|                                   | MtF329 | MtF329 | MtF329 |     | MtF329        | MtF329            | MtF329       |                              | MtF 329                          |      |                 |
| Other (Urological)                |        |        |        |     |               |                   |              |                              |                                  |      |                 |

N = New; P = Previously Cleared by FDA

- [1] Small Organs includes Breast, Thyroid and Testicles  
 [4] Combined modes are: B+M+PW+CFM+PD  
 [6] 3D -  
 [8] VPan  
 [9] XView  
 [13] TP-View

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
 Division of Reproductive, Abdominal and  
 Radiological Devices  
 510(k) Number K081386

# 70 - LA522

| Clinical Application              | Mode of Operations |              |              |     |               |                   |              |                              |                                  |      | Other (specify) |
|-----------------------------------|--------------------|--------------|--------------|-----|---------------|-------------------|--------------|------------------------------|----------------------------------|------|-----------------|
|                                   | B                  | M            | PWD          | CWD | Color Doppler | Amplitude Doppler | Combined [4] | Color Velocity Mapping (TVM) | Tissue Enhancement Imaging (TEI) | CnTI |                 |
| Ophthalmic                        |                    |              |              |     |               |                   |              |                              |                                  |      |                 |
| Fetal                             |                    |              |              |     |               |                   |              |                              |                                  |      |                 |
| Abdominal                         |                    |              |              |     |               |                   |              |                              |                                  |      |                 |
| Intraoperative (Abdominal)        |                    |              |              |     |               |                   |              |                              |                                  |      |                 |
| Intraoperative Neurological       |                    |              |              |     |               |                   |              |                              |                                  |      |                 |
| Pediatric                         | P<br>K051308       | P<br>K051308 | P<br>K051308 |     | P<br>K051308  | P<br>K051308      | P<br>K051308 |                              | P<br>MTF 323                     |      | 6, 8, 9, 13     |
| Small Organ [1]                   | P<br>K051308       | P<br>K051308 | P<br>K051308 |     | P<br>K051308  | P<br>K051308      | P<br>K051308 |                              | P<br>MTF 323                     |      | 6, 8, 9, 13     |
| Neonatal Cephalic                 |                    |              |              |     |               |                   |              |                              |                                  |      |                 |
| Adult Cephalic                    |                    |              |              |     |               |                   |              |                              |                                  |      |                 |
| Cardiac [2]                       |                    |              |              |     |               |                   |              |                              |                                  |      |                 |
| Transesophageal (Cardiac)         |                    |              |              |     |               |                   |              |                              |                                  |      |                 |
| Transesophageal (Non Cardiac)     |                    |              |              |     |               |                   |              |                              |                                  |      |                 |
| Transrectal                       |                    |              |              |     |               |                   |              |                              |                                  |      |                 |
| Transvaginal                      |                    |              |              |     |               |                   |              |                              |                                  |      |                 |
| Transurethral                     |                    |              |              |     |               |                   |              |                              |                                  |      |                 |
| Intravascular                     |                    |              |              |     |               |                   |              |                              |                                  |      |                 |
| Peripheral Vascular               | P<br>K051308       | P<br>K051308 | P<br>K051308 |     | P<br>K051308  | P<br>K051308      | P<br>K051308 |                              | P<br>MTF323                      |      | 6, 8, 9, 13, 14 |
| Laparoscopic                      |                    |              |              |     |               |                   |              |                              |                                  |      |                 |
| Musculo-skeletal Conventional [3] | P<br>K051308       | P<br>K051308 | P<br>K051308 |     | P<br>K051308  | P<br>K051308      | P<br>K051308 |                              | P<br>MTF 323                     |      | 6, 8, 9, 13     |
| Musculo-skeletal Superficial [3]  | P<br>K051308       | P<br>K051308 | P<br>K051308 |     | P<br>K051308  | P<br>K051308      | P<br>K051308 |                              | P<br>MTF 323                     |      | 6, 8, 9, 13     |
| Other (Urological)                |                    |              |              |     |               |                   |              |                              |                                  |      |                 |

N = New; P = Previously Cleared by FDA

[1] Small Organs Includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[4] Combined modes are:

B+M+PW+CFM+PD

[6] 3D

[8] VPan

[9] XView

[13] TP-View

[14] IMT

Concurrence of CDRH, Office of Device Evaluation (ODE)

*[Signature]*

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number K081386

Prescription Use (Per 21 CFR 801.109)

| Clinical Application              | Mode of Operations |         |         |     |               |                   |              |                              |                                  |        | Other (specify) |
|-----------------------------------|--------------------|---------|---------|-----|---------------|-------------------|--------------|------------------------------|----------------------------------|--------|-----------------|
|                                   | B                  | M       | PWD     | CWD | Color Doppler | Amplitude Doppler | Combined [4] | Color Velocity Mapping (TVM) | Tissue Enhancement Imaging (TEI) | CnTi   |                 |
| Ophthalmic                        |                    |         |         |     |               |                   |              |                              |                                  |        |                 |
| Fetal                             |                    |         |         |     |               |                   |              |                              |                                  |        |                 |
| Abdominal                         |                    |         |         |     |               |                   |              |                              |                                  |        |                 |
| Intraoperative (Abdominal)        |                    |         |         |     |               |                   |              |                              |                                  |        |                 |
| Intraoperative Neurological       |                    |         |         |     |               |                   |              |                              |                                  |        |                 |
| Pediatric                         | P                  | P       | P       |     | P             | P                 | P            | P                            | P                                | P      | 6, 8, 9, 13     |
| Small Organ [1]                   | K051308            | K051308 | K051308 |     | K051308       | K051308           | K051308      |                              |                                  | MTF323 |                 |
| Neonatal Cephalic                 | P                  | P       | P       |     | P             | P                 | P            | P                            | P                                | P      | 6, 8, 9, 13     |
| Adult Cephalic                    | K051308            | K051308 | K051308 |     | K051308       | K051308           | K051308      |                              |                                  | MTF323 |                 |
| Cardiac [2]                       |                    |         |         |     |               |                   |              |                              |                                  |        |                 |
| Transesophageal (Cardiac)         |                    |         |         |     |               |                   |              |                              |                                  |        |                 |
| Transesophageal (Non Cardiac)     |                    |         |         |     |               |                   |              |                              |                                  |        |                 |
| Transrectal                       |                    |         |         |     |               |                   |              |                              |                                  |        |                 |
| Transvaginal                      |                    |         |         |     |               |                   |              |                              |                                  |        |                 |
| Transurethral                     |                    |         |         |     |               |                   |              |                              |                                  |        |                 |
| Intravascular                     |                    |         |         |     |               |                   |              |                              |                                  |        |                 |
| Peripheral Vascular               | P                  | P       | P       |     | P             | P                 | P            | P                            | P                                | P      | 6, 8, 9, 13, 14 |
| Laparoscopic                      | K051308            | K051308 | K051308 |     | K051308       | K051308           | K051308      |                              |                                  | MTF323 |                 |
| Musculo-skeletal Conventional [3] | P                  | P       | P       |     | P             | P                 | P            | P                            | P                                | P      | 6, 8, 9, 13     |
| Musculo-skeletal Superficial [3]  | K051308            | K051308 | K051308 |     | K051308       | K051308           | K051308      |                              |                                  | MTF323 |                 |
| Other (Urological)                | P                  | P       | P       |     | P             | P                 | P            | P                            | P                                | P      | 6, 8, 9, 13     |
|                                   | K051308            | K051308 | K051308 |     | K051308       | K051308           | K051308      |                              |                                  | MTF323 |                 |

N = New; P = Previously Cleared by FDA

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[4] Combined modes are:

B+M+PW+CFM+PD

[5] 3D

[8] VPan

[9] XView

[13] TP-View

[14] IMT - MTF 331

Concurrence of CDRH, Office of Device Evaluation (OI)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number

K081386

| Clinical Application              | Mode of Operations |              |              |     |               |                   |              |                              |                                  |             | Other (specify) |
|-----------------------------------|--------------------|--------------|--------------|-----|---------------|-------------------|--------------|------------------------------|----------------------------------|-------------|-----------------|
|                                   | B                  | M            | PWD          | CWD | Color Doppler | Amplitude Doppler | Combined [4] | Color Velocity Mapping (TVM) | Tissue Enhancement Imaging (TEI) | CnTI        |                 |
| Ophthalmic                        |                    |              |              |     |               |                   |              |                              |                                  |             |                 |
| Fetal                             |                    |              |              |     |               |                   |              |                              |                                  |             |                 |
| Abdominal                         |                    |              |              |     |               |                   |              |                              |                                  |             |                 |
| Intraoperative (Abdominal)        |                    |              |              |     |               |                   |              |                              |                                  |             |                 |
| Intraoperative Neurological       |                    |              |              |     |               |                   |              |                              |                                  |             |                 |
| Pediatric                         |                    |              |              |     |               |                   |              |                              |                                  |             |                 |
| Small Organ [1]                   | P<br>K051308       | P<br>K051308 | P<br>K051308 |     | P<br>K051308  | P<br>K051308      | P<br>K051308 | P<br>Mtf323                  | P<br>K051308                     | P<br>Mtf323 | 6, 8, 9, 13     |
| Neonatal Cephalic                 | P<br>K051308       | P<br>K051308 | P<br>K051308 |     | P<br>K051308  | P<br>K051308      | P<br>K051308 | P<br>Mtf323                  | P<br>K051308                     | P<br>Mtf323 | 6, 8, 9, 13     |
| Adult Cephalic                    |                    |              |              |     |               |                   |              |                              |                                  |             |                 |
| Cardiac [2]                       |                    |              |              |     |               |                   |              |                              |                                  |             |                 |
| Transesophageal (Cardiac)         |                    |              |              |     |               |                   |              |                              |                                  |             |                 |
| Transesophageal (Non Cardiac)     |                    |              |              |     |               |                   |              |                              |                                  |             |                 |
| Transrectal                       |                    |              |              |     |               |                   |              |                              |                                  |             |                 |
| Transvaginal                      |                    |              |              |     |               |                   |              |                              |                                  |             |                 |
| Transurethral                     |                    |              |              |     |               |                   |              |                              |                                  |             |                 |
| Intravascular                     |                    |              |              |     |               |                   |              |                              |                                  |             |                 |
| Peripheral Vascular               | P<br>K051308       | P<br>K051308 | P<br>K051308 |     | P<br>K051308  | P<br>K051308      | P<br>K051308 | P<br>Mtf323                  | P<br>K051308                     | P<br>Mtf323 | 6, 8, 9, 13     |
| Laparoscopic                      |                    |              |              |     |               |                   |              |                              |                                  |             |                 |
| Musculo-skeletal Conventional [3] | P<br>Mtf356        | P<br>Mtf356  | P<br>Mtf356  |     | P<br>Mtf356   | P<br>Mtf356       | P<br>Mtf356  |                              | P<br>Mtf356                      | P<br>Mtf356 | 6, 8, 9, 13     |
| Musculo-skeletal Superficial [3]  | P<br>Mtf356        | P<br>Mtf356  | P<br>Mtf356  |     | P<br>Mtf356   | P<br>Mtf356       | P<br>Mtf356  |                              | P<br>Mtf356                      | P<br>Mtf356 | 6, 8, 9, 13     |
| Other (Urological)                |                    |              |              |     |               |                   |              |                              |                                  |             |                 |

N = New; P = Previously Cleared by FDA

[1] Small Organs includes Breast, Thyroid and Testicles

[4] Combined modes are:

B+M+PW+CFM+PD

[6] 3D

[8] VPan

[9] XView

[13] TP-View

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
 Division of Reproductive, Abdominal and  
 Radiological Devices  
 510(k) Number K081386

Prescription Use (Per 21 CFR 801.109)

| Mode of Operations                |              |              |              |              |               |                   |              |                              |                                  |      |                 |
|-----------------------------------|--------------|--------------|--------------|--------------|---------------|-------------------|--------------|------------------------------|----------------------------------|------|-----------------|
| 70 - PA122                        |              |              |              |              |               |                   |              |                              |                                  |      |                 |
| Clinical Application              | B            | M            | PWD          | CWD          | Color Doppler | Amplitude Doppler | Combined [4] | Color Velocity Mapping (TYM) | Tissue Enhancement Imaging (TEI) | CnTI | Other (specify) |
| Ophthalmic                        |              |              |              |              |               |                   |              |                              |                                  |      |                 |
| Fetal                             |              |              |              |              |               |                   |              |                              |                                  |      |                 |
| Abdominal                         |              |              |              |              |               |                   |              |                              |                                  |      |                 |
| Intraoperative (Abdominal)        |              |              |              |              |               |                   |              |                              |                                  |      |                 |
| Intraoperative Neurological       |              |              |              |              |               |                   |              |                              |                                  |      |                 |
| Pediatric                         | P<br>K051308 | P<br>K051308 | P<br>K051308 | P<br>K051308 | P<br>K051308  | P<br>K051308      | P<br>K051308 |                              | P<br>MTF 323                     |      | 6, 9            |
| Small Organ [1]                   |              |              |              |              |               |                   |              |                              |                                  |      |                 |
| Neonatal Cephalic                 | P<br>K051308 | P<br>K051308 | P<br>K051308 | P<br>K051308 | P<br>K051308  | P<br>K051308      | P<br>K051308 |                              | P<br>MTF 323                     |      | 6, 9            |
| Adult Cephalic                    |              |              |              |              |               |                   |              |                              |                                  |      |                 |
| Cardiac [2]                       | P<br>K051308 | P<br>K051308 | P<br>K051308 | P<br>K051308 | P<br>K051308  | P<br>K051308      | P<br>K051308 | P<br>MTF356                  | P<br>MTF 323                     |      | 6, 9            |
| Transesophageal (Cardiac)         |              |              |              |              |               |                   |              |                              |                                  |      |                 |
| Transesophageal (Non Cardiac)     |              |              |              |              |               |                   |              |                              |                                  |      |                 |
| Transrectal                       |              |              |              |              |               |                   |              |                              |                                  |      |                 |
| Transvaginal                      |              |              |              |              |               |                   |              |                              |                                  |      |                 |
| Transurethral                     |              |              |              |              |               |                   |              |                              |                                  |      |                 |
| Intravascular                     |              |              |              |              |               |                   |              |                              |                                  |      |                 |
| Peripheral Vascular               | P<br>K051308 | P<br>K051308 | P<br>K051308 | P<br>K051308 | P<br>K051308  | P<br>K051308      | P<br>K051308 |                              | P<br>MTF 323                     |      | 6, 9            |
| Laparoscopic                      |              |              |              |              |               |                   |              |                              |                                  |      |                 |
| Musculo-skeletal Conventional [3] |              |              |              |              |               |                   |              |                              |                                  |      |                 |
| Musculo-skeletal Superficial [3]  |              |              |              |              |               |                   |              |                              |                                  |      |                 |
| Other (Urological)                |              |              |              |              |               |                   |              |                              |                                  |      |                 |

N = New; P = Previously Cleared by FDA

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[4] Combined modes are:

B+M+PW+CW+CFM+PD

[6] 3D - MTF 356

[9] XView - MTF 336

Concurrence of CDRH, Office of Device Evaluation (ODE)

*April M. Pety*

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number K081386

Prescription Use (Per 21 CFR 801.109)

# 70 - PA230

| Clinical Application              | Mode of Operations |              |              |              |               |                        |              |                              |                                  |             |                 |
|-----------------------------------|--------------------|--------------|--------------|--------------|---------------|------------------------|--------------|------------------------------|----------------------------------|-------------|-----------------|
|                                   | B                  | M            | PWD          | CWD          | Color Doppler | Amplitude Doppler (PD) | Combined [4] | Color Velocity Mapping (TVM) | Tissue Enhancement Imaging (TEI) | CnTI        | Other (specify) |
| Ophthalmic                        |                    |              |              |              |               |                        |              |                              |                                  |             |                 |
| Fetal                             |                    |              |              |              |               |                        |              |                              |                                  |             |                 |
| Abdominal                         | P<br>K051308       | P<br>K051308 | P<br>K051308 | P<br>K051308 | P<br>K051308  | P<br>K051308           | P<br>K051308 | P<br>MTF323                  | P<br>K051308                     | P<br>MTF323 | 6, 9            |
| Intraoperative (Abdominal)        |                    |              |              |              |               |                        |              |                              |                                  |             |                 |
| Intraoperative Neurological       |                    |              |              |              |               |                        |              |                              |                                  |             |                 |
| Pediatric                         |                    |              |              |              |               |                        |              |                              |                                  |             |                 |
| Small Organ [1]                   |                    |              |              |              |               |                        |              |                              |                                  |             |                 |
| Neonatal Cephalic                 |                    |              |              |              |               |                        |              |                              |                                  |             |                 |
| Adult Cephalic                    | P<br>K051308       | P<br>K051308 | P<br>K051308 | P<br>K051308 | P<br>K051308  | P<br>K051308           | P<br>K051308 | P<br>MTF323                  | P<br>K051308                     | P<br>MTF323 | 6, 9            |
| Cardiac [2]                       | P<br>K051308       | P<br>K051308 | P<br>K051308 | P<br>K051308 | P<br>K051308  | P<br>K051308           | P<br>K051308 | P<br>MTF323                  | P<br>K051308                     | P<br>MTF323 | 6, 9            |
| Transesophageal (Cardiac)         |                    |              |              |              |               |                        |              |                              |                                  |             |                 |
| Transesophageal (Non Cardiac)     |                    |              |              |              |               |                        |              |                              |                                  |             |                 |
| Transrectal                       |                    |              |              |              |               |                        |              |                              |                                  |             |                 |
| Transvaginal                      |                    |              |              |              |               |                        |              |                              |                                  |             |                 |
| Transurethral                     |                    |              |              |              |               |                        |              |                              |                                  |             |                 |
| Intravascular                     |                    |              |              |              |               |                        |              |                              |                                  |             |                 |
| Peripheral Vascular               | P<br>MTF356        | P<br>MTF356  | P<br>MTF356  | P<br>MTF356  | P<br>MTF356   | P<br>MTF356            | P<br>MTF356  | P<br>MTF356                  | P<br>MTF356                      | P<br>MTF356 | 6, 9            |
| Laparoscopic                      |                    |              |              |              |               |                        |              |                              |                                  |             |                 |
| Musculo-skeletal Conventional [3] |                    |              |              |              |               |                        |              |                              |                                  |             |                 |
| Musculo-skeletal Superficial [3]  |                    |              |              |              |               |                        |              |                              |                                  |             |                 |
| Other (Urological)                |                    |              |              |              |               |                        |              |                              |                                  |             |                 |

N = New, P = Previously Cleared by FDA

[2] Cardiac is Adult and Pediatric

[4] Combined modes are:

B+M+PW+CW+CFM+PD

[6] 3D -MTF 356

[9] XView - MTF 336

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Joseph M. Wang*

(Division Sign-Off)

Division of Reproductive, Abdominal and  
Radiological Devices  
510(k) Number K081380

Prescription Use (Per 21 CFR 801.109)